1.0 Purpose of Procedure

This document describes Product Resources' process for controlling nonconforming items. It provides for a procedure and assigns responsibilities.

2.0 Scope of Process

The scope of this process is describes how to identify nonconforming items, how to properly quarantine the items from the normal production processes, and what is to be done with the items once identified as nonconforming.

Note: Nonconforming items may be material, product, or services that do not meet requirements or expectations.

3.0 Process Owner(s)

3.1 Quality

4.0 Procedure

4.1 Identification

QC inspectors and production personnel (Assembly, Test) are responsible for the identification of nonconforming items in the course of their activities, including, but not limited to, those described in 91-3003, Verification of Purchased Materials, and 91-4001, Manufacture, Inspection, and Test of Material and Product.

All nonconforming items are documented and identified by the two-part reject tag, form 80-1018. This reject tag is pre-serialized so each tag is unique. The reject tag is physically secured to the nonconforming item(s). The tag includes two major parts, an upper part for identification and a lower part for disposition. To identify the nonconforming item, the upper part of the form must be filled out in its entirety to include:

- Assembly #
- Item # (part #)
- Quantity
- Job/PO #
- Serial/Lot #
- Item Name
- Description of Problem (give as much detail as possible)
- Supplier Defect (Yes if we received the item nonconforming, No if we damaged the item in house, Unknown if we are unsure about the origin of the problem)
- Rejected By (initials of the party recording the problem)
- Date (date that the problem was recorded)

Not all of the above categories will always be applicable. If not applicable, write N/A in the space.

4.2 Segregation

Nonconforming items with their attached reject tags are typically physically segregated from the originating activity, for example an inspection or an assembly job. Nonconforming items may, however, temporarily remain in the originating area if they have already been clearly marked as nonconforming, with reject tags.

Segregation areas include rejected materials quarantine areas and separate, clearly-identified areas in the stockroom and on the production floor.

4.3 Evaluation and Disposition

Nonconforming items are evaluated and dispositioned by any member of the Material Review Board. The Purchasing Manager, Manufacturing Manager, members of Quality, Production Supervisor, Test Manager, and members of Engineering are members of the Material Review Board (also called MRB).

The MRB member making the disposition must understand the problem and the implications of the disposition chosen. MRB members have the authority to involve others in the disposition decision, for example subject matter experts, when needed to gain this understanding. Alternatively, the disposition may be passed to another MRB member.

There are seven possibilities for the disposition of nonconforming items. Their usage is described as follows:

4.3.1 Rework

The nonconforming item is placed back into the manufacturing process to be reworked or repaired. Unless it is obvious, the MRB member making the disposition is to state the intended rework in the allocated Rework Plan/Notes space on the reject tag.

The rework or repair must be completed successfully before its associated nonconforming tag or form is removed. The individual performing the rework or repair shall indicate completion on the tag or form by initials and date. The reworked/repaired item is subject to re-inspection or re-test to demonstrate conformity to existing standards, applicable when the item has a test or inspection called out on a routing.

In choosing a Rework disposition, the potential for adverse effects must be considered. If it is clear that the rework will yield an outcome that meets all specified criteria and characteristics, then this standard Rework disposition can be chosen. If, however, the rework will yield an outcome that may not meet the specified criteria characteristics or may weaken the part (for example, parts that are only meant to be assembled once), then the below Rework with Potential Adverse Effects disposition is to be chosen.

Note this additional policy for medical devices:

If the rework is not obvious and/or must follow a particular process, rework shall be performed to documented instructions. This may take the form of a specially-created rework procedure, a standing procedure for such rework, or rework instructions given in an ECN. Engineering or Quality is responsible for creating these instructions.

4.3.2 Rework with Potential Adverse Effects (Quality or Engineering disposition only)

If the rework may have potentially adverse effects, this disposition shall be authorized by Quality or Engineering only. If a rework plan cannot be conceived that would mitigate the potentially adverse effects, then another disposition must be chosen. If another disposition is chosen, the representative who chose the second disposition will cross out the orginal date of disposition and the original dispositioners initials, and re-initial and date the tag.

All other instructions for Rework apply also here, including the additional policy for medical devices on documented instructions for rework.

4.3.3 Scrap

The nonconforming item is discarded.

4.3.4 Use-As-Is (Quality disposition only)

The nonconforming item is used in the manufacturing process without being reworked or repaired. Depending on customer requirements, the customer may be contacted to obtain permission to use the nonconforming item. This may in turn be coupled with a Product Deviation. See also 91-1003, Customer Communication on the topics of customer notification.

The Use-As-Is disposition shall be authorized by Quality only. The rationale for the use of the nonconforming item must be stated with the disposition.

4.3.5 Re-Test

The possibly nonconforming item is set aside in quarantine until further evaluation can be completed. This disposition is used in situations where there is present doubt of the conformity or nonconformity of the item. Another, final disposition – one of the other dispositions enumerated herein – must follow this interim disposition after evaluation has occurred. In practice, once the possibly nonconforming material has been re-tested, a second disposition will be chosen on the same reject tag. The representative who chose the second disposition will cross out the orginal date of disposition and the original dispositioners initials, and re-initial and date the tag.

4.3.6 Return to Vendor

The nonconforming item is returned to its supplier. It is accompanied by return paperwork which, among other things, must speciffy the reason for the return. It may also be accompanied by a Corrective Action Request of type Supplier. See also 91-7002, Corrective Action.

4.3.7 Void

A reject tag may be dispositioned as Void if the rejection was in error; in other words, the item is conforming. This may be used at any point at which it is realized that the rejection was in error, including following a re-test.

4.4 Completion

The reject tag remains with the nonconforming item until the nonconforming condition is resolved. Once resolved, the red portion of the reject tag remains with the job, and the white portion is forwarded to Quality Control. See also Section 5.0.

5.0 Control of Records

Reject tags are preserved as Quality records. Reject tags, which are serialized, are logged by Quality.

The storage location and retention period for records referenced above are given in 91-6002, Control of Records.